EUROPEAN
COMMISSION

Brussels, 25.7.2018
C(2018) 5037 final

COMMISSION IMPLEMENTING DECISION

of 25.7.2018

concerning the transfer of the designation of "Gemtuzumab Ozogamicin" as an orphan medicinal product under Regulation (EC) No 141/2000 of the European Parliament and of the Council

(Text with EEA relevance)

(ONLY THE ENGLISH, FRENCH AND DUTCH TEXTS ARE AUTHENTIC)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products[1], and in particular the first sentence of Article 5(8) thereof,

Having regard to the application submitted on 7 June 2018 by Pfizer Limited under Article 5(11) of Regulation (EC) No 141/2000,

Having regard to the opinion of the European Medicines Agency, formulated on 7 June 2018 on the transfer of an orphan medicinal product designation,

Whereas:

(1) By Decision C(2000)3025 of 18 October 2000 the medicinal product "Gemtuzumab Ozogamicin" was designated as an orphan medicinal product and entered in the Community Register of Orphan Medicinal Products pursuant to Article 5(9) of Regulation (EC) No 141/2000.

(2) A change of designation holder is a change of an administrative nature, which does not affect the scientific characteristics of the medicinal product already designated as an orphan medicinal product.

(3) The application should therefore be granted,

HAS ADOPTED THIS DECISION:

Article 1

The designation of the medicinal product "Gemtuzumab Ozogamicin" as an orphan medicinal product, entered in the Community Register of Orphan Medicinal Products under number EU/3/00/005 and held by Pfizer Limited, is transferred to Pfizer Europe MA EEIG.

[1] OJ L 18, 22.1.2000, p.1.

Article 2

This Decision is addressed to:
1. Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Bruxelles, Belgique/ Pleinlaan 17, 1050 Brussel, België
and
2. Pfizer Limited, Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom.

Done at Brussels, 25.7.2018

For the Commission

Xavier PRATS MONNÉ
Director-General

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION